

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant : Curt Thies
Serial No. : 10/769,210
Filed : January 30, 2004
Title : BEADING

Art Unit : 1713
Examiner : Kelechi C. Egwim
Conf. No. : 7576

Mail Stop Appeal Brief - Patents

Commissioner for Patents
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APPEAL BRIEF

(i) *Real party in interest.*

Curt Thies

(ii) *Related appeals and interferences.*

None.

(iii) *Status of claims.*

Claims 1-14 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and under the second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, claims 3-14 stand rejected under 35 U.S.C. §101 because the claim presentation of a method results in an improper definition of a process, i.e., and claims 1-15 stand rejected under 35 U.S.C. §102(b) as anticipated by US Patents 3878310, 4070348, 4229547, 4446261, 5326819, 5549908, and 5858534.

(iv) *Status of amendments.*

No amendment was filed subsequent to the final action.

(v) *Summary of claimed subject matter.*

The invention comprises a polymer bead of dried bead structure incorporating a diluent that is highly water soluble characterized by swelling rapidly when placed in contact with

aqueous media to form a water-swollen gel bead. Page 1, lines 7-14. The polymer beads may be a dry-free-flow powder. Page 1, lines 16-17.

According to the method of the invention a polymer bead of dried bead structure incorporating a diluent that is highly water-soluble characterized by swelling rapidly when placed in contact with aqueous media to form a water-swollen gel bead may be made by the water-in-oil process or the droplet extrusion method. Page 5, lines 10-21. Page 5, line 23-page 6, line 5. Page 5, lines 10-21.

Agarose-dextrose beads, a gelatin-dextrose, agarose-maltodextron beads, agarose-dextran beads and agarose-Poly (ethylene glycol) beads may be made by the water-in-oil process. Page 5, line 23-page 8, line 13.

Agarose-Poly (ethylene glycol) beads may also be made by the droplet extrusion method. Page 8, line 14-page 9, line 17.

Polymer beads of dry bead structure incorporating a diluent that is highly water-soluble characterized by swelling rapidly when placed in contact with aqueous media to form a water-swollen gel bead may be used by transporting water-swollen gel beads containing a biological active agent through an animal circulatory system. Page 9, line 18-page 10, line 11. They may be used absorbing a finite amount of biological media at the point they are placed in an animal to serve as a hemostat to reduce hemorrhaging. Page 10, lines 12-16. They may be used for carrying a well defined amount of desired material into a defined small volume element. Page 10, lines 17-24.

(vi) *Grounds of rejection to be reviewed on appeal.*

1. Whether Claims 1-14 fail to comply with the written description requirement.
2. Whether Claims 1-14 fail to particularly point out distinctly claim subject matter which applicant regards as the invention.
3. Whether Claims 3-14 set forth an improper definition of a process.
4. Whether Claims 1-15 are anticipated by US Patents 3878310, 4070348, 4229547, 4446261, 5326819, 5549908, and 5858534.

(vii) *Argument.*

I. CLAIMS 1-14 COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT OF THE FIRST PARAGRAPH OF 35 U.S.C. §112 BECAUSE THE DESCRIPTION SETS FORTH IN DETAIL SPECIFIC EXAMPLES OF THE CLAIMED INVENTION.

The final action states:

2. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the specification supports an initially dry bead structure subsequently incorporated with a water-soluble diluent (i.e., no longer a dry bead), the originally filed specification does not provide support for a polymer bead that is still in a "dry bead structure" while incorporating a diluent.

P.2

This ground of rejection is respectfully traversed. The description states, "A feature of the invention for achieving rapid swelling includes incorporating within the initial dry bead structure a diluent that is highly water soluble." Page 1, lines 10-12. "Rapid swelling beads consists of an intimate mixture of polymer and diluent." Page 2, line 11.

II. CLAIMS 1-14 PARTICULARLY POINT OUT AND DISTINCTLY CLAIM THE SUBJECT MATTER WHICH APPLICANT REGARDS AS THE INVENTION AND CLEARLY DEFINES SWELLING RAPIDLY.

The final action states:

5. The term "swelling rapidly" in claim 1, from which the balance of the claims depend, is still a relative term which renders the claims indefinite. The term "rapidly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The requisite degree of swelling is unclear.

6. Further, claims 11-14 still provide for the use of the beads of claim 1, but, since the claims still do not actually set forth the required steps in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, **positive steps delimiting how this use is actually practiced.**

P. 3

This ground of rejection is respectfully traversed. The description states, "By rapid is meant that primary geometry changes of the bead due to swelling caused by the aqueous medium

occur within 5 to 20 minutes after the beads are placed in contact with an aqueous medium. Bead dimensional changes occurring after this time frame normally are small." P.2, lines 3-5.

Manifestly, one skilled in the art is clearly apprised of the scope of the claimed invention.

Claims 11-14 positively set forth process limitations. Claim 11 calls for "transporting water-swollen gel beads through an animal circulatory system." Claim 12 positively calls for "transporting water-swollen gel beads containing a biological active agent through an animal circulatory system." Claim 13 positively claims "absorbing a finite amount of biological media at the point they are placed in an animal to serve as a hemostat to reduce hemorrhaging." Claim 14 positively recites "carrying a well defined amount of desired material into a defined small volume element."

III. CLAIMS 3, 4 AND 11-14 PROPERLY RECITE METHOD LIMITATIONS, AND CLAIMS 4-10 ARE PROPER PRODUCT-BY-PROCESS CLAIMS.

The final action states:

8. Claims 3-14 are rejected under 35 U.S.C. 101 because the claimed recitation of a method, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). P.3.

This ground of rejection is respectfully traversed. Claims 3 and 4 positively recite the method of making the beads of claim 1 by the water-in-oil process and the droplet extrusion method, respectively. Both methods are fully described in the description. Page 5, line 10-page 6, line 5.

Claims 5-9 are product-by-process claims to beads made by the water-in-oil process described in detail in the description, page 6, line 6-page 8, line 13, and claim 10 is a product-process claim to beads made by the droplet extrusion method described in detail in the description. Page 8, line 14-page 9, line 17.

VI. CLAIMS 1-14 ARE NOT ANTICIPATED BY ANY OF THE REFERENCES BECAUSE NONE OF THE REFERENCES DISCLOSE EACH AND EVERY LIMITATION IN EACH REJECTED CLAIM ARRANGED AS IN THE CLAIM, AT LEAST FAILING TO DISCLOSE RECITED DILUENT.

The final action states:

10. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US3878310, US4070348, US4229547, US4446261, US5326819, US5549908 and US5858534, for reasons cited in the previous action.

13. Regarding the prior art, the claims are indefinite and further comprise new matter. It is still believed by the examiner that the present invention is taught by the cited prior art. P.4

This ground of rejection is respectfully traversed.

"It is well settled that anticipation under 35 U.S.C. 102 requires the presence in a single reference of all of the elements of a claimed invention." *Ex parte Chopra*, 229 U.S.P.Q. 230, 231 (BPA&I 1985) and cases cited.

"Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983).

"This court has repeatedly stated that the defense of lack of novelty (i.e., 'anticipation') can only be established by a single prior art reference which discloses each and every element of the claimed invention." *Structural Rubber Prod. Co. v. Park Rubber Co.*, 223 U.S.P.Q. 1264, 1270 (Fed. Cir. 1984), citing five prior Federal Circuit decisions since 1983 including *Connell*.

In a later analogous case the Court of Appeals for the Federal Circuit again applied this rule in reversing a denial of a motion for judgment n.o.v. after a jury finding that claims were anticipated. *Jamesbury Corp. v. Litton Industrial Prod., Inc.*, 225 U.S.P.Q. 253 (Fed. Cir. 1985).

After quoting from *Connell*, "Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim," 225 U.S.P.Q. at 256, the court observed that the patentee accomplished a constant tight contact in a ball valve by a lip on the seal or ring which interferes with the placement of the ball. The lip protruded into the area where the ball will be placed and was thus deflected after the ball was assembled into the valve. Because of this constant pressure, the patented valve was described as providing a particularly good seal when regulating a low pressure stream. The court quoted with approval from a 1967 Court of Claims decision adopting the opinion of then Commissioner and later Judge Donald E. Lane:

[T]he term "engaging the ball" recited in claims 7 and 8 means that the lip contacts the ball with sufficient force to provide a fluid tight seal. *** The Saunders flange or lip only sealingly engages the ball 1 on the upstream side when the fluid pressure forces the lip against the ball and never sealingly engages the ball on the downstream side because there is no fluid pressure there to force the lip against the ball. The Saunders sealing ring provides a compression type of seal which depends upon the ball pressing into the material of the ring. *** The seal of Saunders depends primarily on the contact between the ball and the body of the sealing ring, and the flange or lip sealingly contacts the ball on the upstream side when the fluid pressure increases. 225 U.S.P.Q. at 258.

Relying on *Jamesbury*, the ITC said, "Anticipation requires looking at a reference, and comparing the disclosure of the reference with the claims of the patent in suit. A claimed device is anticipated if a single prior art reference discloses all the elements of the claimed invention as arranged in the claim." *In re Certain Floppy Disk Drives and Components Thereof*, 227 U.S.P.Q. 982, 985 (U.S. ITC 1985).

None of the references disclose a polymer bead of dry bead structure incorporating a diluent that is highly water-soluble characterized by swelling rapidly when placed in contact with aqueous media to form a water swollen gel bead or methods for making the nonexistent beads. A diluent is free of chemical combination with the dry bead structure. If this ground of rejection were repeated, the Examiner was respectfully requested to quote verbatim the language in each reference regarded as corresponding to each limitation in each rejected claim. The Examiner did not and cannot comply with this request.

Patent No. 4,229,547 discloses a procedure for producing poly(vinylchloride) beads not designed to be water-swellaable are used for any application involving water-swellaable beads. Water simply is the medium in which the beads are produced. Patent No. 5,858,534 discloses only a procedure for producing solid beads that have a hydrophilic surface and are suitable for use as a solid support for the synthesis of complex organic compounds and in bioassays. There is no disclosure of a diluent that is highly-water soluble characterized by swelling rapidly when placed in contact with aqueous media to form a water-swollen gel bead.

Patent Nos. 3,878,310, 4,070,348, 4,229,547, 4,446,261, 5,326,819 and 5,549,908 disclose the production of water-swellaable beads, that are formed as a result of a chemical cross-linking reaction, not from a diluent that is highly water-soluble characterized by swelling rapidly

when placed in contact with aqueous media to form a water-swollen gel bead. In the first five patents, bead formation is a result of the chemical polymerization of one or more vinyl monomers, wherein one or more of the vinyl monomers contains the multiple functionality necessary for a chemical cross-linking reaction. The polymer disclosed in the last patent is a natural polymer, a polysaccharide. That polymer is freely water soluble until it is chemically cross-linked. Accordingly, this patent discloses the chemical cross-linking of a water-soluble polysaccharide polymer in bead form to thereby produce water-swallowable and hydrolytically labile beads or microspheres, but there is no disclosure of a polymer bead of dry bead structure incorporating a diluent that is highly water soluble characterized by swelling rapidly when placed in contact with aqueous media to form a water-swollen gel bead.

The claimed processes produce the novel beads without forming chemical cross-links. These processes produce the novel beads by secondary valence interactions and not chemical reactions.

The lack of these chemical reactions is particularly advantageous for assorted health care and bio science applications because the beads thus produced must meet regulatory agency specifications before they can be used in either external or internal applications that involve humans and food source animals. Chemical reactions of any sort raise questions with regulatory agencies.

An important aspect of the claimed invention is the incorporation of the freely water-soluble diluent.

The claimed beads have a number of features. They have spherical geometry when dry and in water-swollen states. Spherical beads are advantageous because they pass freely through narrow openings like steering needles without causing plugging that may occur with irregularly shaped particles. The novel beads produced by the novel claimed methods have spherical geometry.

The claimed dry beads swell rapidly when placed in water. Primary or major size changes occur within minutes after contact with water. This feature is especially advantageous when the beads are used in intra-arterial infusion therapy. The beads can be stored dry until the time of use, be placed in suitable injection media and then injected within a reasonable time frame without concern about bead size changes that occur slowly. Further, the novel beads may

be placed at the site of a contusion where they would rapidly absorb fluid being exuded, for example, thereby blocking or reducing further fluid flow.

A dry polymer bead without the diluent disclosed and claimed in this application when placed in water undergoes significant size changes over multiple hour periods because bead swelling is limited by the slow rate at which water penetrates and swells a dry bead without the diluent. Incorporation of the freely water-soluble diluent into the bead disclosed and claimed in this application accelerates the solvation and swelling process because it furnishes the incoming water with a large driving force for hydration of the polymer that forms the primary structure of the bead. This large driving force for hydration causes the bead to rapidly swell to its equilibrium size in the aqueous medium in which it is placed.

A surprising characteristic of the invention disclosed and claimed in this application is that the diluent can be incorporated into the beads formed from a gellable polymer without destroying the gel-forming properties of the polymer. Expressed differently, it is surprising that a polymer, such as agarose, that gels under appropriate conditions in aqueous media, can accommodate a significant freely water-soluble diluent and still exist as a gel. Retention of this gel formation property in the presence of a freely water-soluble diluent that does not by itself gel is advantageous in connection with the formation of spherical beads having the advantages noted above.

The water-swollen beads formed when placed in contact with aqueous media according to the invention are very soft and deformable. This deformability is advantageous for many applications, such as intra-arterial infusion therapy. This feature is also advantageous when incorporated into personal products placed in contact with the skin.

The absence in the prior art of the novel beads precludes rejecting the novel methods of producing the non-existent products.

"In the absence of the article in the prior art we find no basis for the conclusion that the manipulative steps of assembling the nonexistent article would be obvious." *Ex parte Rubin*, 127 U.S.P.Q. 286, 287 (Bd. of Appeals 1959).

The authorities upon which the Examiner relies are not in point.

Ex parte Dunki, 153 U.S.P.Q. 678, 679 (Bd. of Appeals 1967) cited *Clinical Prod., Ltd. v. Brenner*, 149 U.S.P.Q. 475 (D.D.C. 1966), and there the court said “that a proper process or method claim should recite at least one process step” *Id.* 477.

Claim 11 recites “transporting water-swollen gel beads through an animal circulatory system.”

Claim 12 recites “transporting water-swollen gel beads containing a biological active agent through an animal circulatory system.”

Claim 13 recites “absorbing a finite amount of biological media at the point they are placed in an animal to serve as a hemostat to reduce hemorrhaging.”

Claim 14 recites “carrying a well defined amount of desired material into a defined small volume element.”

Each is “a proper process or method claim ...[that] recite[s] at least one process step.”

CONCLUSION

In view of the foregoing authorities, reasoning, and the inability of the prior art to anticipate, suggest or make obvious the subject matter as a whole of the claimed invention, the decision of the Examiner finally rejecting all the claims should be reversed. If the Board believes a claim may be allowed in amended form, the Board is respectfully requested to include

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an explicit statement that such a claim may be allowed in such amended form and direct that Appellant shall have the right to amend in conformity with such statement in the absence of new references or grounds of rejection.

The brief fee of \$250 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050, Order No. 04015-005001.

Respectfully submitted,
FISH & RICHARDSON P.C.

Date: June 21, 2006

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(viii) *Claims appendix.*

1. Polymer bead of dry bead structure incorporating a diluent that is highly water-soluble characterized by swelling rapidly when placed in contact with aqueous media to form a water-swollen gel bead.
2. Polymer beads in accordance with claim 1 that are a dry-free-flow powder.
3. A method of making the beads of claim 1 by water-in-oil process.
4. The method of making the beads of claim 1 by the droplet extrusion method.
5. Agarose-dextrose beads made by the method of claim 3.
6. Gelatin-dextrose beads made by the method of claim 3.
7. Agarose-maltodextrin beads made by the method of claim 3.
8. Agarose-dextran beads made by the method of claim 3.
9. Agarose-Poly (ethylene glycol) beads made by the method of claim 3.
10. Agarose-Poly (ethylene glycol) beads made by the method of claim 4.
11. The method of using the beads of claim 1 in accordance with transporting water-swollen gel beads through an animal circulatory system.
12. The method of using the beads of claim 1 in accordance with transporting water-swollen gel beads containing a biological active agent through an animal circulatory system.
13. The method of using the beads of claim 1 in accordance with absorbing a finite amount of biological media at the point they are placed in an animal to serve as a hemostat to reduce hemorrhaging.
14. The method of using the beads of claim 1 in accordance with carrying a well defined amount of desired material into a defined small volume element.

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(ix) *Evidence appendix.*

None

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(x) *Related proceedings appendix.*

None